



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/914,020 | 12/31/2001 | Yuehua Li | 5051-4511P | 8515 |
| 20792 | 7590 | 11/05/2003 | EXAMINER | |
| MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627 | | | EPPS FORD, JANET L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1635 | |

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/914,020 | LI ET AL. | |
| | Examiner | Art Unit | |
| | Janet L. Epps-Ford, Ph.D. | 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25,35-50 and 55-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25,35-50 and 55-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4, 6-22, 24-25, and 37-41, and 46-50, drawn to peptide based inhibitors of mucus secretion and methods of use.

Group II, claims 1, 5-9, 17-18, 22-23, 35-36, and 42-45, drawn to antisense based inhibitors of mucus secretion and methods of use.

Group III, claims 51-61, drawn to a method of screening a test compound for the ability to bind a MARCKS protein.

2. The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The inventions according to Groups I-III are related to compositions, and methods for inhibiting mucus secretion comprising administering to a cell a compound that inhibits MARCKS protein-related mucus secretion, however the corresponding technical feature of the inventions according to Groups I-III is not free of the prior art. Therefore, the technical feature shared among these groups cannot be considered a "special technical feature."

For example, Graff et al. discloses peptides derived from the 25 amino acids comprising the phosphorylation site domain of the MARCKS protein, in particular Graff et al. discloses a

Art Unit: 1635

peptide identical to SEQ ID NO: 2 of the instant application, see page 35, Example 5 of the instant application. Absent evidence to the contrary, the teachings of Graff et al. anticipates at least claim 39 of the instant application, which recites a pharmaceutical formulation comprising a mucus-inhibiting peptide fragment of MARCKS. Moreover, Ali et al. discloses antibodies targeting the MARCKS protein (p. 190). Absent evidence to the contrary the teachings of Ali et al. would anticipated instant claim 61.

3. Additionally, the inventions according to Groups I and II are drawn to the use of chemically and structurally distinct forms of inhibitors of mucus secretion, possessing distinct modes of operation and distinct modes of functional activity. Moreover, Group III is drawn to an entirely different process than the processes set forth in Groups I-II. However, according to 37 CFR § 1.475(d) Applicants are not entitled to multiple processes.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

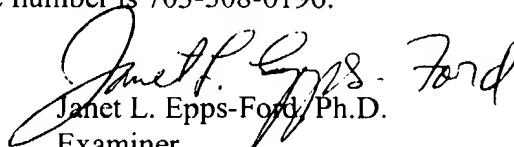
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1635

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on Monday-Thursday, 8:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE